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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,310	04/29/2005	Kaoru Okakura	Q87626	2360

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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT PAPER NUMBER

1652

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,310	<b>Applicant(s)</b> OKAKURA ET AL.	
	<b>Examiner</b> Iqbal Chowdhury, Ph.D.	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 and 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10 and 11 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/05/06</u> | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This application is a 371 of PCT/JP03/14013 filed on 10/31/2003.

The preliminary amendment filed on 4/29/2005 amending claims 6, and 9-21 is acknowledged. Claims 1-21 are pending.

Applicant's election with traverse of Group I, Claims 1-5 and 10-11, drawn to an isolated polypeptide cellulase and a composition containing the same and SEQ ID NO: 3 as a species in the response filed on 2/7/2006 is acknowledged.

The traversal is on the ground(s) that according to the IPER, there is no lack of unity, however, examiner finds that lack of unity exists because if a product is known then product lacks special technical feature and there is no contribution over the prior art. Examination in the national phase is not bound by the international phase findings.

Applicants also argue that SEQ ID NO: 3 (Group A), 4 (Group B) and 5 (Group C) are novel derived from SEQ ID NO: 1 that is not persuasive. SEQ ID NO: 3 (Group A), 4 (Group B) and 5 (Group C) are structurally and functionally different from each other. The shared technical feature of Group A-C is related by the special technical feature of SEQ ID NO: 1, however, the cellulase of claim 1, part (2), SEQ ID NO: 1 could be any cellulase wherein one or more amino acids are added or deleted with no limit on the extent of modification, and such a cellulase is disclosed in WO01/90375, which is therefore, known in the art. The cellulase polypeptides of SEQ ID NO: 3, 4 and 5 are not required to make this determination of whether this technical feature is a contribution over the prior art.

The requirement is still deemed proper and is therefore made **FINAL**.

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Claims 4-5, 6-9 and 12-21 and species proteins (A)-(B) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-3, and 10-11 are under consideration and are being examined herein.

***Priority***

Acknowledgement is made of applicants claim for foreign priority JP2002-318303 filed on 10/31/2002.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to a genus of a polypeptide molecule of modified or variant of cellulase having one or plural amino acid residues are added or deleted to SEQ ID NO: 1. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid residues added or deleted to SEQ ID NO: 1. Thus the genes includes scope of the claim includes numerous structural variants with the potentiality of obtaining inactive cellulases, as no function

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is apparent following the mutational modifications. Although the specification states that these types of changes are routinely done in the art, the specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 1 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. The applicant was not in possession of the claimed genus.

Claims 1 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cellulase polypeptide having a mutation (substitution) of 162<sup>nd</sup> amino acid residue of the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for any modified cellulase or any one or plural amino acid residues are added to or deleted from the N-terminus of the amino acid sequence of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 1 is so broad as to encompass a genus of protein molecule encoding any modified cellulase or any one or plural amino acid residues are added to or deleted from the N-terminus of the amino acid sequence of SEQ ID NO: 1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of mutants

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by one or plural amino acid residue added to or deleted from the N-terminus of the amino acid sequence of SEQ ID NO: 1 broadly encoded by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only two mutation of the claimed modified protein.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any modified cellulase or any one or plural amino acid residues are added to or deleted from the N-terminus of the amino acid sequence of SEQ ID NO: 1 because the specification does not establish: (A) regions of the protein structure which may be modified without effecting cellulase activity; (B) the general tolerance of modified cellulase protein to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any cellulase protein

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residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any modified cellulase or any one or plural amino acid residues are added to or deleted from the N-terminus of the amino acid sequence of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any modified cellulase or any one or plural amino acids residues added to or deleted from the N-terminus of the amino acid sequence of SEQ ID NO: 1 having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Murashima et al. (WO01/90375, publication date 11/29/2001, foreign priority date of JP00/0150463, 5/22/2000, see IDS, citation #1 of 4/29/2005). Murashima et al. disclose the

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sequence of a modified protein (SEQ ID NO: 1) having 223 amino acids residues, which is 100% identical to SEQ ID NO: 1 and 98.8% identical to the SEQ ID NO: 3 (only difference in 162<sup>nd</sup> position of the amino acid sequence) of the instant application, having endoglucanase or cellulase activity as part (2) of claim 1 recites one or plural amino acids are added to deleted from N-terminus of the amino acid sequence of SEQ ID NO: 1. Murashima et al. also disclose the isolation of the gene from *Humicola insolens*, cloning the gene in expression vector and expression in host cells followed by purification. Murashima et al. further disclose a cellulase preparation and a washing solution for treating cellulose-containing fabrics to reduce fuzziness, improve its touch and appearance and color of the fabrics. Murashima et al do not disclose mutation at 162<sup>nd</sup> amino acid position of SEQ ID NO: 1.

#### ***Allowable Subject Matter***

Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

##### **Status of the claims:**

Claims 1-3 and 10-11 are pending.

Claims 1 and 10-11 are rejected.

Claims 2 and 3 are objected.

No claim is in condition for allowance.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

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